

Document Information:

Sponsor/Owner	Westat
Protocol/Project	CTSU
Function/System	Randonode
Document	Maintenance Log

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Day-to-Day document updates are captured in section 5.

Approvals:

Signatures are controlled at the request process level.

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1. References

#	Name	Location
1	Westat SOP Glossary	SOP Area
2	Computer Dictionary, 5 th Edition, Microsoft Press	Library Area
3	Westat IT-102 Systems Change Control (SCC)	SOP Area
4	Westat IT-111 Systems Maintenance and Calibration SOP	SOP Area
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2. Definitions, Acronyms, and Abbreviations

The reader is referred to the System Glossary [reference #1] for general and study specific terminology. The reader is referred to the Microsoft Press Computer Dictionary [reference #2] for computer specific terminology.

3. Introduction

This maintenance log provides information about OPEN system modifications and maintenance. This log will include modifications and maintenance only for OPEN portal side.

4. Process

Westat uses a controlled and documented change control process on the system. The process is fully described in the change management SOP [reference #3] and the system maintenance SOP [reference #4].

RandoNode Maintenance Log

5. Maintenance Log

The following table provides a reference to maintenance and modification activity for the Java RandoNode Starter Kit.

Description	Randonode Version	Completed By/Date	Modified Files	Comments
<ol style="list-style-type: none"> Associated items, failure message with overrides. Added items extraction and persistence logic. Added utility methods to methods to retrieve list of overrides, override items by failure message and override items by override code. Fixed duplicate item retrieval issue from different modules. Enhanced Response and display messages in case meta data file is not available. Introduced utility methods to retrieve metadata version oid and to extract the OPEN date string from metadata version oid. Modified date format extraction while reading input data string from file. Introduced API to format clinical data date string to any valid SimpleDateFormat from YYYYMMDD. Introduced API to convert any valid SimpleDateFormat string to java date. Modified XML tag extraction due to change in case while reading input data string from file. Old clinical data files can not be used due to this change. 	1.0.5.0	Sushmita De/12-16-2008	ClinicalDataUtil.java, hibernate.cfg.xml, OdmUtil.java, OverrideApproval.hbm.xml, OverrideApproval.java, OverrideItems.hbm.xml, OverrideItems.java, RandoNodeApp.java, RandoNodePersistClinical.java, RandoNodePersistMeta.java, RegistrationNSABP.java, RegistrationNSABPB42.java, RegistrationXML.java, Application.xml, OpenPortalProxy.java	Please update hibernate.cfg.xml with the latest version.
<ol style="list-style-type: none"> Manual Registration handled in doRegister method. Test Registration handled in registration classes. Improved response population in registration classes. getRegistrar() method was commented since site registrar was not considered. Example to retrieve registrar provided in the registration classes. New class CodeListItem was introduced to represent CodeListItem of clinical data. CodeList population and persist logic was modified, now codeList will have the list of codeList items to hold multiple codedValue, translatedText and ranks. Introduced User fax and numeric data significantDigit extraction logic. Introduced following utility methods for meta data: <ol style="list-style-type: none"> Retrieve meta data file name and path. Check if an item is recurring Retrieve significantDigits for an item. Retrieve codelist translated text by item detail and coded value. Retrieve codelist translated text by codeList 	1.0.6.0	Sushmita De/03-04-2009	RegistrationNSABP.java, RegistrationNSABPB42.java, Person.hbm.xml, RandonodeClient.java, ClinicalDataUtil.java, CodeList.java, CodeListItem.java, hibernate.cfg.xml, MetaDataUtil.java, User.java, RandoNodePersistMeta.java,	

RandoNode Maintenance Log

Description	Randonode Version	Completed By/Date	Modified Files	Comments
<p>oid and coded value.</p> <p>8. Introduced following utility methods for clinical data:</p> <ol style="list-style-type: none"> Introduced getUserByCtepld method, can be used to retrieve registrar. Retrieve site registrar. Retrieve Data entry person and location. Retrieve tracking number and protocol for the current transaction <p>9. getItemList method was commented since it did not distinguish between modules and this private method was not used.</p> <p>10. Readme.doc was updated to describe configuration file, Application.XML setup.</p> <p>11. New client class RandonodeClient.java was introduced. This class accepts sample clinical XML file as input and send data to RandoNode web service.</p>				
<ol style="list-style-type: none"> Introduced new web methods getPatientData and getVersion. Modified doValidate and doRegister method to verify existing patient. Implemented doRegisterTest method. Introduced verification of operation attribute in all the web methods. Introduced Demography and ExistingPatient objects within RegistrationResponse. Introduced new attributes within OpenRegistration object and demonstrated their application in web methods. Modified the valid values of OpeRegistration.status attribute. Modified existing User class to support multiple OpenUserTypes. Introduced following utility methods in CliicalDataUtil class. <ul style="list-style-type: none"> getStandardDemographyObject– Retrieves Standard Demography Data if present in request. getUsersByOpenUserType – Retrieves User List by OpenUserType getAvailableOpenUserTypes - Returns list of all openUserType available within current registration request. isCTSUDataEntryPerson – Verifies if data entry person belongs to CTSU. Introduced following utility method in MetaDataUtil class. <ul style="list-style-type: none"> getCodeListItemByCodedValue – Retrieves CodeListItem object by CodeList oid and coded value. 	1.1.0.0	Sushmita De/04-26-2009	ExistingPatient.java, Demography.java, OpenRegistration.java, RegistrationResponse.java, RandoNode.java, RandoNode.wsdl, ClinicalDataUtil.java, MetaDataUtil.java, OdmUtil.java, DemographicsPublicIdMapping.xml, ZString.java, ZAppBlock.java, Application.xml, build.properties, build.xml, Person.hbm.xml, User.java, RandoNode.sql, RandoNodeApp.java, RegistrationCore.java, OpenTxBlock.java, RegistrationXML.java, GetVersion.java, IsAvailable.java, RandonodeClient.java, OpenPortalProxy.java, OpenRequestObjects.xml, RegistrationNSABP.java, RegistrationNSABPB42.java	
<ol style="list-style-type: none"> Modified existing logic of getPatientData and doValidate. These methods now demonstrate how to retrieve existing data from database and use for processing. Introduced following utility methods in OdmUtil class. 	1.1.0.1	Sushmita De/05-12-2009	RegistrationNSABP.java, RegistrationNSABPB42.java, RandoNodeApp.java, antlr-2.7.6rc1.jar,	antlr-2.7.6rc1.jar replaced existing ant-antlr-1.6.5.jar.

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<ul style="list-style-type: none"> a. dateToString b. getXsdFormatDateTime <p>3. Introduced following utility methods in HibernateImpl class.</p> <ul style="list-style-type: none"> a. searchBySqlQueryNParam b. searchBySqlQuery c. searchByQuery d. findByLikeCondition 			HibernateImpl.java, OdmUtil.java, HibernateUtil.java, ClinicalDataUtil.java, ZAppBlock.java, RegistrationXML.java, OpenResponse.hbm.xml, OpenRegistrations.java, OpenRegistration.hbm.xml	
<ul style="list-style-type: none"> 1. Introduced embedded and ancillary study support to existing RandoNode. Modified the WSDL file, interfacing objects and sample web methods for the same. 2. Introduced new attribute purpose within ItemGroup and added code to retrieve the value from meta data XML. 3. Introduced methods to populate ancillary registration array from sample clinical data XML file. 4. Updated domain objects to persist the new attributes. 5. Added attributes in WSDL to override credentialing exception and for case notes. 6. Introduced the following utility methods in ClinicalDataUtil class. <ul style="list-style-type: none"> a. getItemDataListByItemItemGroupStudy b. getAncillaryStudies c. getAncillaryStudiesToProcess d. getActionByAncillaryStudy 7. Introduced the following utility methods in MetaDataUtil class. <ul style="list-style-type: none"> a. getMainStudyName b. getStudiesByItem c. getStudyByItemItemGroup d. getStudyByItemGroup e. getItemsByStudy f. getItemsByItemGroupStudy g. getItemsByItemOidItemGroupStudy h. getItemGroupByModNameStudy i. getItemGroupsByStudy 	2.0.0.0	Sushmita De/11-19-2009	RandoNode.wsdl, RandoNodeApp.java, RegistrationNSABP.java, RegistrationNSABPB42.java, ClinicalDataUtil.java, ZAppBlock.java, RegistrationXML.java, RandoNodePersistInterface.java, RandonodeClient.java, OpenRegistrations.java, OpenRegistration.java, OpenRegistration.hbm.xml, OpenPortalProxy.java, MetaDataUtil.java, ItemGroup.java, ItemGroup.hbm.xml, HibernateUtil.java	

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<ul style="list-style-type: none"> 8. Added a new doValidate operation VALIDATE_PRE_REQUISITES 9. Added example codes to validate Prerequisite data within the doValidate method 10. Added additional Item and ItemGroup ODM attributes to the domain objects for future use 11. Added APIs to extract the new ItemGroupDef and ItemDef ODM attributes. This is to extract all the remaining Item and ItemGroup attributes for future use 12. Added new ClinicalDataUtil APIs to identify and retrieve Prerequisite ItemData: <ul style="list-style-type: none"> a. getPreRequisitItemDataList b. getPreRequisitItemDataListByStudy 13. Added new MetaDataUtil APIs to identify and retrieve Prerequisite ItemData: <ul style="list-style-type: none"> a. getPreRequisitItemGroups b. getPreRequisitItemGroupsByStudy c. getPreRequisitItems d. getPreRequisitItemsByStudy 	2.0.1.0	Sushmita De/04-08-2011	RegistrationNSABP.java, ZAppBlock.java, ClinicalDataUtil.java, ItemGroup.java, Item.java, MetaDataUtil.java, RandoNodeApp.java, Index.htm, OpenRequestObjects.xml	
<ul style="list-style-type: none"> 1. OpenRegistrations constructor is modified to accept four new NCI reporting attributes – treatmentAssignmentCode, treatmentAssignmentDescription, subgroupCode, diseaseCode 2. The framework class ZAppBlock is modified to include three string constants representing Transfer & Update Module (T&UM) operations 3. The doRegister, doRegisterTest and doRegisterAncillary method implementations are updated to provide example how the NCI reporting attributes should be set and when to perform the T&UM operations. In addition, a new method setDiseaseCode is added to show how to set the disease code 4. A new utility method is added to convert HashMap list values to xml string for OpenRegistration.otherValue construction 5. The RandoNodeApp.getVersion method is updated to version 3.0.0.0 	3.0.0.0	Phoebe Whitefield /07-30-2014	OpenRegistrations.java, OpenRegistration.java, RandoNodeApp.java, ZAppBlock.java, ClinicalDataUtil.java, RegistrationNSABP.java	